

# VALIDATION OF BUCCAL/SALIVA SAMPLES AND FINGER PRICK BLOOD SAMPLE COLLECTED WITH COPAN FLOQSWABS TO DETECT HUMAN CYTOMEGALOVIRUS IGG ANTIBODIES

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## INTRODUCTION:

Infection with cytomegalovirus (CMV) is very common with seropositivity rates ranging from 40% in developed countries up to 100% in developing countries. CMV transmission may occur by salivary contact or by blood transfusion, therefore all stem cells, bone marrow, solid organs and blood donors and prenatal patients must be screened in order to determine the CMV immunity. The enzyme-linked immunosorbent assay (ELISA) is the most commonly used serologic test for measuring antibody to CMV. A positive test for CMV IgG indicates that a person was infected with CMV at some time during their life. A blood sample is usually used for CMV immunity testing therefore participants to donors or prenatal screening programs are discouraged to participate due to the blood collection procedure. A non-invasive sample like saliva/buccal swab would be more acceptable for CMV antibody screening.

## OBJECTIVE:

To test and validate buccal buccal/saliva swabs (BSS) and finger prick blood samples, collected with FLOQSwabs™ for the detection of CMV IgG, as an alternative to serum samples obtained by venipuncture, for screening donors and prenatal patient.

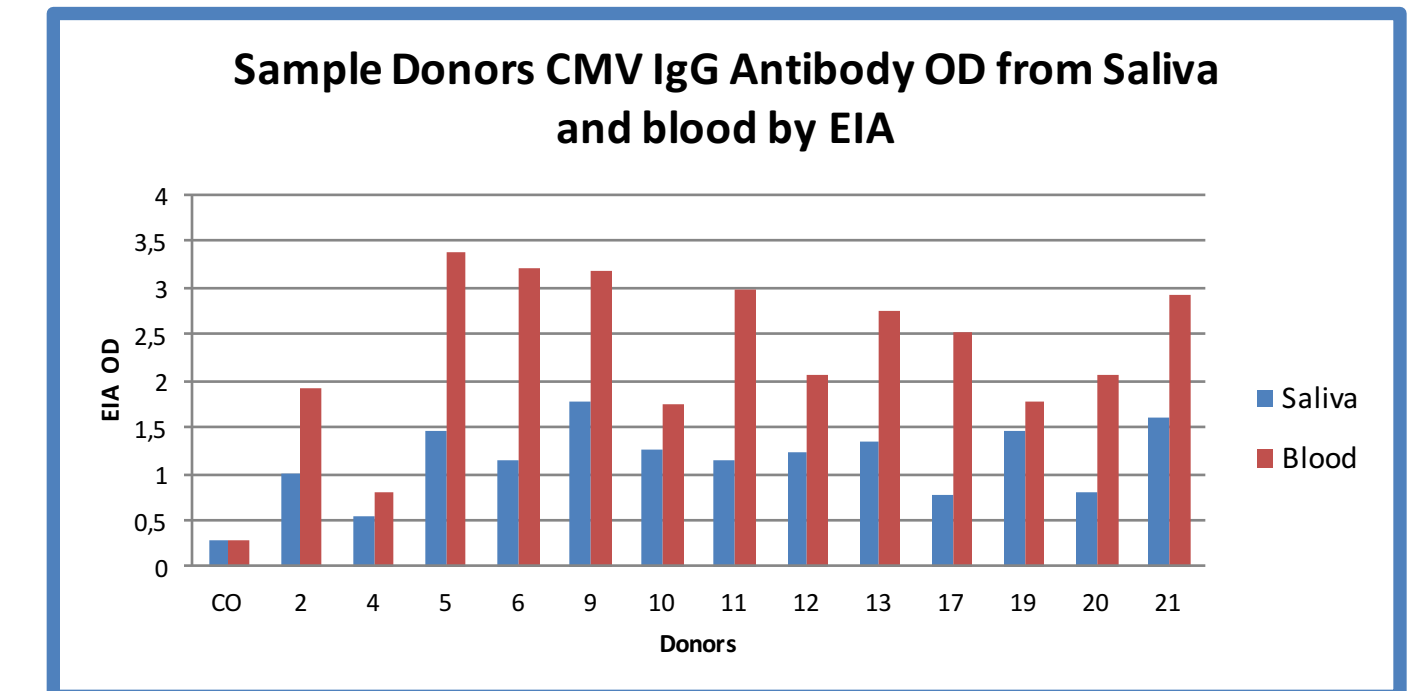
## MATERIALS:



## METHODS:

- Ten known HCMV seronegative were tested to define the cut off of the buccal saliva swabs (BSS) and the finger prick blood swab (FPBS). Fifty donors were tested by BSS and FPBS to evaluate results concordance between results obtained from serum samples.
- FLOQSwabs™ (Copan Italia, Brescia Italy) were used to collect buccal buccal/saliva swabs (BSS) and finger prick blood swab samples (FPBS).
- BSS samples were collected by placing the swab on the tongue and wetting the swab for 5 seconds, and then by rotating the swab 10 times in both left and right gingival sulcus.
- FPBS samples were collected using a disposable finger prick device to prick the finger skin and blood was collected with a FLOQSwabs™ with a 30 mm breaking point.
- BSS and FPBS swabs were left to air at room temperature until completely dry (for at least 2 hours) and then stored in their own plastic tubes and sent to the laboratory.
- In the laboratory each BSS and FPBS swab was broken in a conical micro-tubes containing a basket and stored at room temperature until testing. If basket were not available, after breaking the FLOQSwabs™ was transferred swabs tip up in a fresh micro-tube.
- Prior testing 200 ul of PBS solution was added to each tube, vortexed and left at room temperature for 15 minutes then centrifuged at high speed on a microfuge for 1 minute.
- FLOQSwabs™ and baskets were removed and the eluates were used for serologic testing.
- HCMV IgG antibody determination was performed on serum samples collected from controls and patients with the assay used in the laboratory for HCMV screening.
- Since the CMV IgG amount is lower in saliva than in serum, eluates of BSS and FPBS were tested with a sensitive in-house developed ELISA assay ( Revello et al., J. Infect. Dis 2002;186:553-7. Negative controls were used to define the cut offs.

## RESULTS:



Controls Donors (N)	HCMV Serostatus	BSS Results	FPBS Results
Controls 10	Negative	Negative	Negative
Donors 34	Positive	Positive	Positive
Donors 16	Negative	Negative	Negative

- Cut off values for IgG determination on BSS and FPBS samples were established using the average of the results obtained with 10 HCMV seronegative donors.
- All 50 patients were correctly identified, 34 as HCMV IgG-positive and 16 as IgG-negative on both BSS and FPBS samples.

## CONCLUSION:

- CMV IgG results agreement, obtained by testing BSS and FPBS samples, was 100% concordance compared with the results obtained from serum samples.
- These preliminary validation results are indicating that both BSS and FPBS samples collected with FLOQSwabs™ can be used for determination of HCMV-specific IgG antibodies.
- Collection of saliva sample with FLOQSwabs™ is less invasive and more acceptable to patient and donors for CMV immunity status screening of stem cells, bone marrow, and solid organs donations.
- In addition, the same buccal/saliva sample collected with FLOQSwabs™ can be used for detection of HCMV DNA shedding by real time PCR.